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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,521	02/18/2005	Gideon Schreiber	05558.0018.PCUS00	7709

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,521	SCHREIBER, GIDEON	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *62-86* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-61 have been cancelled and new claims 62-86 have been added by the amendment dated June 30, 2004.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I claims 62-75,81 drawn to an IFNAR2 polypeptide, having mutations at amino acid residues 78 and 100, wherein said mutations synergistically increase the polypeptide's affinity for IFN-β; derivatives of said polypeptide, and a method of expressing and producing an IFNAR2 polypeptide.

Group II, claims 76-80, drawn to a DNA encoding an IFNAR2 polypeptide, having mutations at amino acid residues 78 and 100, a vector capable of expressing said polypeptide and a host cell comprising said vector and polypeptide.

Group III, claim 82 drawn to a composition comprising an IFNAR2 polypeptide, having mutations at amino acid residues 78 and 100, wherein said mutations synergistically increase the polypeptide's affinity for IFN-β and optionally an IFN antagonist.

Group IV, claim(s) 83-86, drawn to a method of treating a condition associated with modulation of IFN comprising administering to a patient a composition comprising an IFNAR2 polypeptide, having mutations at amino acid residues 78 and 100, wherein said mutations synergistically increase the polypeptide's affinity for IFN-β and optionally an IFN antagonist.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475 (c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475 (d) states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and §1.476(c)."

In view of 37 CFR 1.475 (c) and 37 CFR 1.475 (d), Group I is considered the main invention that is drawn to the first product, first mentioned in the claims of the application (i.e. a polypeptide) and the first recited invention drawn to other categories related thereto (i.e. a method of expressing said polypeptide).

Group II-IV claims are drawn to multiple distinct processes of use and multiple distinct products that do not share the same inventive concept as in Group I. The claimed inventions of Groups II-IV recite distinct materials and/or method steps that are neither required nor recited in the claimed invention of Group I, and thus have their own technical features, e.g. a DNA and vector (Group II), a polypeptide and antagonist (Group III), and a method of treatment (Group IV). Further, each of the groups has a technical feature not required for the other groups.

For example, the polypeptide of Group I which is composed of amino acids, and nucleic acids of Group II, which are composed of purine and pyrimidine units, are structurally distinct molecules. Furthermore, the information provided by the nucleic acid of Groups II can be used to make a materially different protein or polypeptide than that of Group I. For example, a nucleic acid that hybridizes to sequences encoding IFNAR2, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with IFNAR2. The Groups are also distinct inventions because the protein product can be made by other and materially distinct processes, such as chemical synthesis. In addition, nucleic acids can be used for processes other than the production of protein, such as DNA hybridization assays. Further, searching the inventions of Groups containing nucleic acids and those encoding proteins, together would impose a serious search burden. In the instant case, the search of the protein sequence and nucleotide sequences are not coextensive. The composition of Group III is distinct from the polypeptide of Group I since it may include an antagonist of IFN that may be defined by any number of structures or elements that are not present in the polypeptide of Group I. Further, the composition of

Group III is not required for the polypeptide of Group I or the nucleic acid of Group II and *vice versa*. The treatment method of Group IV is distinct from the polypeptide of Group I, since Group IV claims are directed to a separate category of invention involving administration of a composition that may be distinct from the products of inventions pertaining to Groups I-III.

Each invention is directed to a distinct goal, which comprises the use of separate products or methods in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I to IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A specifically named single species of amino acid that is to be substituted for asparagines 100, as recited in claim 64; a specifically named single species of polypeptide corresponding to one SEQ ID NO, as recited in claim 66; and a specifically named disease or condition as recited in claims 83, 84, 85, and 86.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 64, 66, 83, 84, 85, and 86, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 64, 66, 83, 84, 85, and 86.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical features (amino acids, polypeptides of SEQ ID NO: 2,3,4; cancer, autoimmune and viral disease) linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Thus, it would be unduly burdensome for the examiner to search all the claimed inventions being sought in the pending claims.

Applicant is advised that the reply for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(571) 272-0532**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(571) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00 am-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on **(571) 272-0731**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199**.

Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER